

Serial No.: 10/537,014
Atty. Docket No.: P70598US0

REMARKS

The Office Action mailed June 26, 2007, has been carefully reviewed and, by this Amendment, Applicant has canceled claim 3, amended claims 1, 2 and 4-21 and added claims 22 and 23. Claims 1, 2 and 4-23 are pending in the application. Claims 1, 21 and 23 are independent.

The Examiner rejected claims 1-4, 10, 14, 16-18 and 21 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,934,721 to Juster et al. ("Juster"). Under 35 U.S.C. 103(a), the Examiner rejected claims 5-9, 12 and 13 as being unpatentable over Juster in view of U.S. Patent No. 5,429,613 to D'Amico, rejected claims 15 and 19 as being unpatentable over Juster in view of U.S. Patent No. 5,147,341 to Starke et al., and rejected claim 20 as being unpatentable over Juster in view of U.S. Patent No. 4,204,527 to Wu et al.

As an initial matter, Applicant notes that concurrent with the filing of the above-captioned application under 35 U.S.C. 371, a Preliminary Amendment was filed in order to remove multiple dependencies in the claims. Inadvertently, claim 1 as presented within that Preliminary Amendment did not correspond with claim 1 from the International Preliminary Examination Report (IPER). Since claim 1 from the IPER represents the subject matter Applicant

intended to claim, claim 1 has been amended herein to substantially correspond with claim 1 from the IPER.

More specifically, as set forth in amended claim 1, the present invention is directed to a catheter with a conduit for draining body fluid from at least one inlet opening in a proximal, insertable, end of the catheter to at least one outlet opening. The catheter includes first and second parts, with the first part forming the proximal end and the second part forming the distal end. The first and second parts are joined in a fixed connection. In addition, the first part is at least partly encapsulated in a sleeve so as to leave at least a portion of the second part of the catheter uncovered by the sleeve. The sleeve is attached to the catheter with a seal that forms a liquid and/or bacteria tight barrier to maintain the sterility of at least the encapsulated portion of the first part. *This sealed connection between a sleeve and the catheter that encapsulates at least a portion of the proximal first part of the catheter to form a liquid and/or bacteria tight barrier therefor is not shown or suggested by the prior art.*

Juster discloses a catheter 31 having a flexible shaft 33 that extends along a major extent of its length within a tube sheath 21. Both the catheter and the sheath are then wholly

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contained within an outer package for storage and marketing. The sheath, which is comparatively rigid so as to retain its own shape, is provided in order to prevent the catheter shaft, which is made of "highly flexible and bendable soft latex rubber" from sliding down in the package and kinking (see column 1, lines 24-33; column 2, lines 25-30). The sheath in Juster is not, however, attached to the catheter and certainly is not "sealed" thereto so as to form a liquid and/or bacteria tight barrier protecting the sterility of the insertable end of the catheter. On the contrary, while one end of the sheath is sealed to itself by heat seal 25 to form a closed end, the opposite end of the sheath is open (see column 2, line 63 to column 3, line 1); neither end of the sheath is attached to the catheter.

Similarly, no portion of the outer package 13 of Juster is attached to the catheter either. Hence, while the outer package maintains the sterility of the catheter and tube sheath in a sealed zone pocket of the outer package, the zone pocket is only peripherally sealed and is not attached to the catheter (see column 1, line 65 to column 2, line 5). Clearly, the outer package cannot be interpreted as a sleeve that is sealed to the catheter with a seal that forms a liquid and/or barrier tight barrier between the sleeve and the catheter as claimed by the present invention.

Amended claim 21 sets forth a sleeve for a catheter, the latter having inlet openings in its insertable end. The sleeve includes an oblong body with a cavity for sealingly enclosing at least a part of the catheter and an opening for inserting the catheter into the cavity. The cavity forms a cap portion that covers the inlet openings of the catheter when the catheter is arranged in the cavity. The sleeve includes a seal member opposite the cap portion that sealingly secures the sleeve to the catheter to form a liquid and/or bacteria tight barrier therebetween. Such sealing *between the sleeve and the catheter* is not shown or suggested by the prior art for the same reasons as already discussed in connection with claim 1.

New claim 23 is also patentable over Juster for at least the same reasons as claims 1 and 21. In addition, claim 23 states that the first part of the catheter is at least partly encapsulated in the sleeve and at least a portion of the second part of the catheter is uncovered by the sleeve *when the catheter is in its storage configuration*. Also while in the storage configuration, the sleeve is attached to the catheter with a seal that forms a liquid and/or bacteria tight barrier between the sleeve and the catheter where they are attached to one another to maintain sterility of the encapsulated portion of the first catheter part

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while the uncovered portion of the second catheter part remains exposed for handling thereof. This partial covering and partial exposure of the catheter parts while in the storage configuration is certainly not contemplated by Juster which instead requires that the complete catheter and tube sheath be sealed within a sealed outer package container 13 for storage (see, e.g., column 1, lines 34-37; column 2, lines 3-5).

For at least the foregoing reasons, claims 1, 21 and 23 are allowable over the prior art. Favorable consideration and allowance thereof is requested. Claims 2, 4-20 and 22 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein. Particularly, the prior art does not disclose a seal between the sheath and the catheter as set forth in claim 1 that remains intact during both storage and use of the catheter, as provided in claim 19.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance.

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Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By Harvey B. Jacobson, Jr.
for Reg. No. 40,495
Reg. No. 20,851

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
Telephone: (202) 638-6666
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